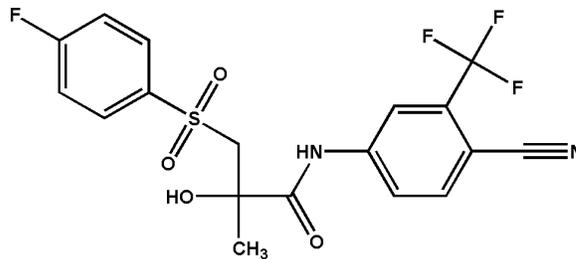




U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

# USP Certificate

## Bicalutamide LOT G0I298



### Molecular Formula

**C<sub>18</sub>H<sub>14</sub>F<sub>4</sub>N<sub>2</sub>O<sub>4</sub>S**

### Molecular Weight

**430.37**

### CAS Number

**90357-06-5**

### LABEL TEXT



#### USP REFERENCE STANDARD

**BICALUTAMIDE 200 mg**

Danger! Suspected of causing cancer. May damage fertility or the unborn child.

Do not dry. For quantitative applications, use a value of 0.997 mg of bicalutamide per mg of material on the as is basis.

Keep container tightly closed. Protect from light. Store in a refrigerator.



USP, 12801 Twinbrook Pkwy, Rockville, MD, +1-301-881-0866  
CAT No. 1071202 Material mfd in Hungary

**Intentionally over-labeled for GHS compliance**

For use with specified USP compendial monographs, use only after GPOC prior to use at [www.usp.org/9848](http://www.usp.org/9848).

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection, if exposed or concerned. Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

USP certifies that the USP Reference Standards Committee, in accordance with their rules and procedures, determined that this USP Reference Standard lot is suitable to assess compliance with the monograph standards for which it is specified. The critical characteristics of this lot are usually determined independently in three or more laboratories, including USP, academic, and industrial collaborators.

*Jeri L. Joth*

QA Director

### **Calculation Value**

Unless otherwise stated on the Reference Standard label, a value of 100.0% should be used in USP or NF compendial applications for which the use of this Reference Standard is intended. Please refer to the specific Reference Standard label for further information.

### **Expiration**

Current lots are identified in the Official USP Reference Standards catalog. In some cases, the previous lot may still be considered official. If so, it is identified in the column marked "Previous Lot/Valid Use Date." Ordinarily, the previous lot is carried in official status for about one year after the current lot enters distribution.

It is the responsibility of each user to determine that this lot is current when used. To ensure up-to-date information, USP publishes the Official USP Reference Standards Catalog, which contains official lot designations. This information is also available on the USP web site, at [www.usp.org](http://www.usp.org), as well as in the bimonthly subscription publication, *Pharmacopeial Forum*.

### **Instructions for Use**

Follow the instructions in the appropriate USP or NF Monographs and General Requirements for Tests and Assays of the current *USP–NF*. In the event that instructions on the label of this lot differ from those found in the current *USP–NF*, those on the label supersede any instructions listed in Chapter <11>.

### **Non-Monograph Use**

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

---

## **LEGAL NOTICE**

USP MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE ACCURACY, COMPLETENESS, OR CURRENTNESS OF THIS CERTIFICATE; AND USP SPECIFICALLY DISCLAIMS ANY OTHER WARRANTY, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. USP DOES NOT WARRANT THAT THE INFORMATION CONTAINED HEREIN MEETS THE CUSTOMER'S REQUIREMENTS. USP SHALL NOT BE LIABLE ON ACCOUNT OF ANY SUCH ERRORS OR OMISSIONS.

USP Reference Standards are not intended for use as drugs, dietary supplements, or as medical devices.  
This document is not a Material Safety Data Sheet.

This certificate may not be reproduced without the express written permission of USP.

Copyright 2009 The United States Pharmacopeial Convention, Inc. All rights reserved.